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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,856

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EXAMINER

DAHLE, CHUN WU

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,856	Applicant(s) TSUCHIYA ET AL.	
	Examiner CHUN DAHLE	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/31/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment to the claims, filed on April 1, 2009, is acknowledged.

Claims 6-8 have been canceled.

Claims 13-15 have been added.

Claims 1-5, 9-12 and newly added claims 13-15 are pending.

Claims 10-12 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 6, 2008.

Claims 1-5, 9, and newly added claims 13-15 are currently under consideration as they read on originally elected invention of a sugar chain-altered anti-HM1.24 antibody.

2. Applicant's IDS, filed on December 31, 2008, is considered.
3. This Office Action will be in response to applicant's arguments, filed on April 1, 2009.

The rejections of record can be found in the previous Office Action, mailed on January 6, 2009.

4. A new BIB sheet is provided herein to correct an apparent typographical error for the filing date of the Japanese foreign priority application JAPAN 2003-207165. The correct filing date for JAPAN 2003-207165 should be 08/11/2003 rather than 08/01/2003 (see page 3 of the Application Data Sheet filed on February 10, 2006).

5. Applicant's rejoinder request for the withdrawn method claims (claims 10-12) filed on April 1, 2009, is acknowledged. However, the event of rejoinder only applies when the elected

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claims directed to the products are found allowable. Given that the elected product claims (drawn to an antibody) have been rejected for reasons of record (see discussion below), the process claims will not be rejoined at this time.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5, 9, and newly added 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kanda et al. (US Patent Application 2003/0115614, reference on PTO-892 mailed on January 9, 2008) for reasons of record.

Applicant's arguments, filed on April 1, 2009, have been fully considered but have not been found persuasive.

Applicant argues that the claims have been amended and now recite the structure of the N-glycoside linked sugar containing a bisecting N-acetylglucosamine (GlcNAc) which is bound with a β 1,4-linkage on the mannose. Applicant asserts that Kanda et al. do not teach the newly added limitations with respect to the N-glycoside linked sugar structure as recited in claims 1 and 13-15. Applicant further argues that claim 9 now encompasses the requirement for the antibody to have a relative ratio of all fucose-free sugar 30% or more in all sugar chains on the antibody, which is not taught by the reference. Applicant argues that reference is not enabled for a total fucose-free sugar chain about 30% as recited in claim 9 because the reference only teaches 20% of the fucose-free sugar chain. Thus, applicant asserts that the reference teachings do not anticipate the claimed invention.

This is not found persuasive for following reasons:

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In contrast to applicant's assertion that the prior art does not teach the claimed N-glycoside linked sugar structure, it is noted that the recited sugar structure would be considered inherent properties of the prior art anti-HM1.24 antibody because the structure of the N-glycoside linked sugar is determined by the host cells used to produce the antibody. Given that both the instant and prior art antibodies are made in the same host cells, YB2/0 (ATCC CRL-1662), that carry the same deficiency in α 1,6 fucosyltransferase (e.g. see Example 1 on pages 34-37 of Kanda et al. and Examples on page 12), the recited sugar structure would be inherent properties of the prior art antibody. Indeed, Kanda et al. clearly teach the anti-HM1.24 antibody produced in YB2/0 host cells wherein said antibody does not comprise α 1,6 core fucose but comprises bisecting N-GlcNAc bound with a β 1,4 linkage on the mannose and wherein only 47% of said antibody comprises α 1,6 core fucose which translates to 53% of the N-glycoside linked sugar chains do not have α 1,6 core fucose (e.g. see paragraph [0702]-[0703]). In addition, Kanda et al. teach other antibodies produced in YB2/0 cells also show more than 30% of fucose-free sugar chains (e.g. see Example 8 on pages 43-45). Thus, the reference teachings meet the claimed "wherein of all sugar chains on said antibody the relative ratio of all fucose-free sugar chains is 30% or more" as recited in claim 9.

Regarding the sugar chain structure recited in newly added claims 13-15, it is noted that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). See MPEP 2112. Thus, the claiming of the sugar chain structure which is inherently present in the prior art antibody does not make the claim patentable. The identification and characterization of the N-glycoside linked sugar chain structure of the anti-HM1.24 antibody does not make it novel. Therefore, applicant's arguments have not been found persuasive.

8. Conclusion: no claim is allowed.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644